

Safety Alert

April 2025

Vardenafil –Risks of Stevens-Johnson syndrome SJS ,toxic epidermal necrolysis (TEN) and Central serous chorioretinopathy

EDA performs label update to include the following:

Special warnings and precautions for use

Severe cutaneous adverse reactions

Stevens-Johnson syndrome (SJS)/toxic epidermal necrolysis (TEN) which may be life-threatening or fatal have been reported in association with treatment with vardenafil.

If signs or symptoms suggestive of these reactions appear, the medication should be discontinued immediately. treatment with vardenafil and should not be restarted in this patient at any time.

Effects on vision

Visual disturbances, including central serous chorioretinopathy (CSC)

Undesirable effects

Skin and subcutaneous tissue disorders

Not known: Stevens-Johnson syndrome (SJS)/toxic epidermal necrolysis (TEN)

Eye disorders

Not known: Central serous chorioretinopathy (CSC)

Background:

Therapeutic Indication

Treatment of erectile dysfunction in adult men. Erectile dysfunction is the inability to achieve or maintain an erection sufficient for satisfactory sexual intercourse

Background on safety concern:

- Stevens-Johnson syndrome (SJS) is a rare, serious disorder of the skin and mucous membranes. It's usually a reaction to medication that starts with flu-like symptoms, followed by a painful rash that spreads and blisters. Then the top layer of affected skin dies, sheds and begins to heal after several days.
Stevens-Johnson syndrome is a medical emergency that usually requires hospitalization. Treatment focuses on removing the cause, caring for wounds, controlling pain and minimizing complications as skin regrows. It can take weeks to months to recover.
- A more severe form of the condition is called toxic epidermal necrolysis (TEN). It involves more than 30% of the skin surface and extensive damage to the mucous membranes.
- Central serous chorioretinopathy, commonly referred to as CSC, is a condition in which fluid accumulates under the retina, causing a serous (fluid-filled) detachment and vision loss.

References:

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